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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,427	02/13/2001	Joseph P. Steiner	22789XA-T	3405

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GUILFORD PHARMACEUTICALS C/O  
FOLEY & LARDNER  
3000 K STREET, NW  
WASHINGTON, DC 20007-5143

EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/781,427

Applicant(s)

STEINER ET AL.

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The final rejection has been withdrawn and prosecution is reopened in view of the rejections that follow.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claim is drawn a pharmaceutical composition which comprises (i) rapamycin and (ii) a second hair revitalizing agent. On page 1 it recites that "This invention relates to pharmaceutical compositions and methods for treating alopecia and promoting hair growth..." Therefore, the phrase "revitalizing agent" is understood by one of ordinary skill in the art to mean "treating alopecia and promoting hair growth."

2) State of the prior art.

There are two commercially available compounds which are used to induce hair growth, minoxidil and finasteride.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Thousands of compounds have been screened for potential use to induce hair growth and treat alopecia, but currently there are only two commercially available products.

4) Level of predictability in the art.

The art pertaining to inducing hair growth and treating alopecia remains highly unpredictable. Thousands of compounds have been screened for potential use to induce hair growth and treat alopecia, but there are still only two commercially available products.

5) Amount of direction and guidance provided by the inventor.

Figs. 2-5 provide data that six of the thousands of compounds included in the claims yield new hair growth. Rapamycin is not one of the compounds. Furthermore,

Iwabuchi et al (reference EA) disclose in Table I (page 66) that the application of rapamycin to the dorsal skin surface of mice did not initiate new hair growth.

6) Existence of working examples.

There is no data that demonstrates that rapamycin yields new hair growth. Furthermore, Iwabuchi et al disclose in Table I (page 66) that the application of rapamycin to the dorsal skin surface of mice did not initiate new hair growth.

7) Breadth of claims.

The claim is narrow. It recites a pharmaceutical composition comprising rapamycin and a second hair revitalizing agent.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The data disclosed by Iwabuchi et al demonstrates that the composition of claim 17 is not enabled. Iwabuchi et al disclose that rapamycin does not yield growth of hair.

Claims 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the phrase "an effective amount of rapamycin." It is not clear if the effective amount is an amount in which the rapamycin treats alopecia, or whether the effective amount is an amount in which the rapamycin is effective as an immunosuppressive as described at the bottom of page 1 and the top of page 2 of the instant specification.

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There is no antecedent basis in claims 11, 16, 17, 18, 19 for the phrase "a second hair revitalizing agent." It is not clear that the first recited compound is a hair revitalizing agent.

The use of small Roman numbers in claim 11, "(iv)," "(v)" and "(vi)" are confusing, since the claim does not recite "(i)," "(ii)" or "(iii)." Furthermore, in the specification the components are referred to as "(i)," "(ii)" and "(iii)."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-14 are rejected under 103(a) as being unpatentable over McElwee et al and applicants' disclosure on page 2 in view of 5,620,908 (Samour).

McElwee et al disclose that FK506, a compound containing a 6-membered heterocyclic ring with a single nitrogen heteroatoms, which has an N-linked diketo substituents attached to the heterocyclic ring and which is additionally substituted with an ester substituent attached to the heterocyclic ring, grows hair (page 494, left column, lines 1+) and suggests its use to treat alopecia areata (page 496, left column, second paragraph). Said compound meets the description of the first compound in the pharmaceutical composition of claim 11, thereby rendering it obvious. The instant claims do not exclude FK506.

The specification (page 1, lines 25 through page 2, line 19) discloses that FK506 is an immunosuppressant.

The instant claims differ over the reference in reciting a composition comprising a second hair revitalizing agent. It is noted that the specification discloses on page 1 that the invention relates to pharmaceutical compositions for treating alopecia and promoting hair growth. Therefore, it is obvious that the instant intent of the phrase "hair revitalizing" includes promoting hair growth and treating alopecia. Furthermore, Samour (col. 1, lines 17-20) discloses that minoxidil is used to treat hair loss.

Furthermore, "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven* 105 USPQ 1069. Therefore, in the absence of a showing of unexpected results, it would be obvious to one of ordinary skill to combine FK506 and minoxidil to yield the instant composition, since each is individually taught in the prior art to be useful to promote hair growth.

Claims 12 and 13 differ over McElwee and applicants' disclosure in reciting that the compound has an affinity for an FKBP-type immunophilin. However, it would be inherent that FK506 has the recited affinity for FKBP-type immunophilin since the specification discloses (page 11, second paragraph) that the compounds of the instant invention have said affinity because FK506 is a compound having the structure recited for the first compound in claim 11.

***Double Patenting***

Upon reconsideration the obviousness-type double patenting rejection over 09/784,174 will not be maintained. The first compound of the instant composition has a six-membered heterocyclic ring, while the first compound of the composition of 09/784,174 may have a seven-membered heterocyclic ring.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
**REBECCA COOK**  
**PRIMARY EXAMINER**  
**GROUP 1200/614**

December 11, 2003